REMARKS

The Office action dated April 2, 2009 and the cited reference have been carefully considered.

Status of the Claims

Claims 1-14 are pending.

Claims 2-9 and 12-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 12-14 are rejected under 35 U.S.C. § 101 for reciting a use without setting forth any steps involved in the process of using.

Claims 1-7 and 9 are rejected under 35 U.S.C. § 102(b) or 102(e) as being anticipated by Rosenberg et al. (U.S. Patent 6,579,544; hereinafter "Rosenberg").

Claims 1-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg.

Claim 2 is canceled. Therefore, the rejection of this claim is now moot.

Claims 1 and 3-14 remain in the current prosecution following entry of his amendment.

The Applicant respectfully traverses the rejections of claims 1 and 3-14 for the reasons set forth below.

Remarks on the Amendments

Supports for "a daily dosage" and for the ranges of amounts of lutein, zeaxanthin, copper, zinc, vitamin C, and vitamin E are found, for example, in paragraphs 0034-0040 and paragraphs 0086-0090 of the original specification, as filed.

Support for "free of beta-carotene" is found, for example, in paragraph 0046 of the original specification, as filed.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 2-9 and 12-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, specifically for reciting a broad range and a narrower preferable range within the same claim, and/or for reciting an open-ended group. Claim 2 is canceled. Therefore, the rejection of this claim is now moot. Claims 3-9 and 12-14 are amended to cure these deficiencies where applicable. Therefore, Applicant respectfully submits that this rejection is now overcome. Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 101

Claims 12-14 are rejected under 35 U.S.C. § 101 for reciting a use without setting forth any steps involved in the process of using.

Claim 12 is amended to recite a process of manufacturing a micronutrient product comprising preparing a mixture, and forming the mixture into a daily dosage unit.

Claims 13 and 14 are amended to recite a method of supplementing a balanced diet of a subject, said method comprising administering to said subject a micronutrient combination product.

Therefore, Applicant respectfully submits that amended claims 12-14 now overcome this rejection. Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 102(b) or 102(e)

Claims 1-7 and 9 are rejected under 35 U.S.C. § 102(b) or 102(e) as being anticipated by Rosenberg. Claim 2 is canceled. Therefore, the rejection of claim 2 is now moot. Applicant respectfully traverses the rejection of claims 1, 3-7, and 9 because Rosenberg does not disclose each and every element of each of claims 1, 3-7, and 9.

"Anticipation requires the presence in a single prior art reference disclosure each and every element of the claimed invention, *arranged as in the claim.*" *Lindemann*

Maschinenfabrik GmbH v. American Hoist & Derrick Co., 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984) (emphasis added). The "arranged as in the claim" requirement refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely as a catalog of separate parts, in disregard of the part-to-part relationships set forth in the claims that give the claims their meanings. Lindemann Maschinenfabrik GmbH, 221 U.S.P.Q. at 485. The test is thus more accurately understood to mean "arranged or combined in the same way as in the claim." "[Un]less a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." Net MoneyIN, Inc. v. Verisian, Inc., 545 F.3d 1359, 1369. "[The] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference" (emphasis in original)." In re Arkley, 455 F.2d 586, 587 (C.C.P.A. 1972).

First, Rosenberg does not disclose any composition that comprises lutein, zeaxanthin, copper, and zinc and is <u>free of beta-carotene</u>. Wherever Rosenberg has lutein, zeaxanthin, copper, and zinc, he always has beta-carotene. See Rosenberg's Formulations I and II, column 23.

In contradistinction, claims 1, 3-7, and 9 recite a product that is free of beta-carotene.

Second, Rosenberg does not disclose the daily dosage composition, in terms of enumerated ingredients and their amounts. It is impossible to infer from Rosenberg's disclosure such daily dosage composition. Rosenberg discloses individual amounts of ingredients in milligrams or micrograms for Formulations I-VIII. But what is a "Formulation" here? One cannot say whether it is a daily dosage. Rosenberg discloses the numbers of "daily rations" of 4-9 for different persons in column 24, lines 20-49. But what constitutes a "daily ration"? How much is a "daily ration"? Rosenberg discloses that a formulation can be encapsulated in a "00" capsule, each containing 1.0-1.3 mg/ml (column 24, lines 58-60). But what is the volume of a "00" capsule? Without disclosing the volume of a capsule, Rosenberg does not teach how much material (in mg) each capsule contains. In addition,

what is the relationship between a capsule and a daily ration? Nobody knows. Thus, Rosenberg does not teach all of the limitations combined in the same way (into a daily dosage) as recited in the instant claims. *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Rosenberg does not clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by Rosenberg's teachings. *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972).

Since Rosenberg does not disclose each and every element of each of claims 1, 3-7, and 9, Rosenberg does not anticipate these claims.

Claim Rejection Under 35 U.S.C. § 103(a)

Claims 1-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg. Applicant respectfully traverses this rejection because the Examiner has merely identified separate ingredients but has not provided any articulated reason <u>based on facts or scientific principles</u> why one of ordinary skill in the art would have arrived at a <u>daily dosage comprising the recited amounts of ingredients</u>.

A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. It is important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

The Board of Patent Appeals and Interferences, in *Ex parte Whalen* (BPAI, July 23, 2008), emphatically stated that it is not good enough merely to show that each of the elements of a claim is known in the prior art. The Examiner must provide reasoned, <u>fact-based explanation</u> supported by the evidence of record, or <u>scientific reasoning</u>, to establish the reasonableness of the examiner's belief. Pages 8, 12, and 13, quoting *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (BPAI 1986). "[O]bviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition." Page 16. Again, such showing must have a reasoned,

fact-based explanation supported by the evidence of record, or scientific reasoning, to establish the reasonableness of the Examiner's belief. The Examiner bears the initial burden of proving unpatentability. *Tafas v. Doll* (Fed. Cir., March 20, 2009, Slip Op. p. 30). And that burden of persuasion remains with the Examiner. *Id.* at p. 16. To discharge that burden in a case of claim rejection under 35 U.S.C. § 103(a) over a combination of references, the Examiner must set fort articulated fact-based or scientific reasoning why a person of ordinary skill would have combined the teachings of the references at the time of the invention, as instructed by the Supreme Court and the Court of Appeals for the Federal Circuit.

Here, the Examiner merely pointed out that Rosenberg discloses lutein, zeaxanthin, copper, zinc, vitamin C, and vitamin E. Rosenberg does not even disclose a single formulation that meets the limitations of the instant claims. Specifically, Rosenberg does not teach or suggest any formulation that comprises lutein, zeaxanthin, copper, and zinc and is free of beta-carotene. Moreover, Rosenberg does not teach or suggest a daily dosage comprising the recited ingredients in recited amounts.

As pointed out above, it is impossible to infer what Rosenberg intended a daily dosage to be. And the Examiner has not set forth any fact-based or scientific reasoning for how one could have arrived at specific amounts of ingredients in a daily dosage.

Since the Examiner has not set forth any reason for how one of ordinary skill in the art could have arrived, from the teaching of Rosenberg, at the beta-carotene free daily dosage composition of instant claims 1 and 3-14, these claims are patentable over Rosenberg under 35 U.S.C. § 103(a).

In view of the above, it is submitted that the claims are patentable and in condition for allowance. Reconsideration of the rejection is requested. Allowance of the claims at an early date is solicited.

Respectfully submitted,

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